

Amendments to the Claims

The following listing of claims will replace all prior versions and listings of claims in the application.

1. (Currently amended) A process for the preparation of a dispersion of nano-crystalline particles in an aqueous medium, the process comprising: ~~combining:~~
 - (a) combining:
 - (i) a first solution comprising a substantially water-insoluble substance in a water-miscible organic solvent, and ~~[with; b)]~~
 - (ii) an aqueous phase comprising water and optionally a stabiliser, to form a dispersion of amorphous particles; ~~[e) and]~~
 - (b) sonicating the dispersion of amorphous particles ~~[for a sufficient period]~~ to form nano-crystalline particles of the substantially water-insoluble substance; and
 - (c) optionally removing the water-miscible organic solvent.
2. (Currently amended) [A] The process according to claim 1, wherein the nano-crystalline particles have a mean particle size of from 50 to 250nm.
3. (Currently amended) [A] The process according to claim 1, ~~[or 2]~~ wherein the substantially water-insoluble substance is a ~~[substantially water-insoluble]~~ pharmacologically active compound.
4. (Currently amended) [A] The process according to ~~[any one of the preceding claims]~~ claim 1, wherein the concentration of the substantially water-insoluble substance in the combined solution and aqueous phase following step (a) ~~[(b) of the process]~~ is 10 mM or less.
5. (Currently amended) [A] The process according to claim 4, wherein the concentration of the substantially water-insoluble substance in the combined solution and aqueous phase following step (a) ~~[(b)]~~ is from 0.5 to 3 mM.

6. (Currently amended) [A] The process according to ~~[any one of the preceding claims]~~ claim 1, wherein the aqueous phase contains a stabiliser.
7. (Currently amended) [A] The process according to claim 6, wherein the stabiliser comprises a polymeric dispersant and an amphiphilic surfactant.
8. (Currently amended) [A] The process according to claim 7, wherein the ~~[stabiliser comprises a polymeric dispersant and]~~ amphiphilic surfactant is an anionic, cationic, or non-ionic surfactant.
9. (Currently amended) [A] The process according to claim 8, wherein the polymeric dispersant is polyvinylpyrrolidone and the anionic surfactant is sodium dodecyl sulfate.
10. (Currently amended) [A] The process according to ~~[any one of claims 7 to 9]~~ claim 7, wherein the amphiphilic surfactant is at a concentration below the ~~[amphiphilic polymer]~~ critical association concentration for the amphiphilic surfactant and polymeric dispersant.
11. (Currently amended) [A] The process according to ~~[any one of the preceding claims]~~ claim 1, wherein ~~[the combination of]~~ the first solution and the aqueous phase ~~[is carried out with]~~ are combined by rapid mixing.
12. (Currently amended) [A] The process according to claim 11, wherein rapid mixing comprises using sonication during the combination.
13. (Currently amended) [A] The process according to ~~[any one of the preceding claims]~~ claim 1, wherein ~~[the combination of]~~ the first solution and the aqueous phase ~~[is carried out]~~ are combined in less than 30 seconds.
14. (Currently amended) [A] The process according to ~~[any one of the preceding claims]~~ claim 1, wherein the first solution is added to the aqueous phase.

15. (Currently amended) [A] The process according to ~~[any one of the preceding claims]~~
claim 1, wherein the dispersion of amorphous particles ~~[formed following combination of the~~
~~first solution and the aqueous phase]~~ is sonicated for at least 10 minutes ~~[(preferably from 20 to~~
~~100 minutes)]~~.
16. (Currently amended) [A] The process according to ~~[any one of the preceding claims]~~
claim 1, wherein the dispersion of amorphous particles is sonicated ~~[sonication takes place]~~ at a
temperature below 50°C.
17. (Currently amended) [A] The process according to ~~[any one of the preceding claims which~~
~~further comprises]~~ claim 1, further comprising isolating the nano-crystalline particles from the
aqueous medium.
18. (New) The process according to claim 15, wherein the dispersion of amorphous particles is
sonicated for 20 to 100 minutes.
19. (New) The process according to claim 1, wherein:
the first solution is added to the aqueous phase, wherein the aqueous phase comprises
water, a polymeric dispersant, and an amphiphilic surfactant, and
the concentration of the substantially water-insoluble substance in the combined first
solution and aqueous phase following step (a) is 10mM or less.
20. (New) The process according to claim 19, wherein the first solution and aqueous phase are
combined by rapid mixing using sonication during the combination.